

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/617,038
				Filing Date	July 11, 2003
				First Named Inventor	Andersen et al
				Group Art Unit	1614 1645
				Examiner Name	SWARTZ
Sheet	1	of	1	Attorney Docket Number	SSISAUSA

OTHER PRIOR ART-NONPATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), column(s), number(s), publisher, city and/or country where published	T ²
RJS	MM	SINIGAGLIA ET AL, "A Malaria T-Cell Epitope Recognized in Association with Most Mouse and Human MHC Class II Molecules", Nature, Vol. 336, 6201, pp. 778-780, (December 22-29, 1988)	
Examiner Signature	R.P. Swartz		Date Considered 10-19-05

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETE FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, Washington, DC 20231. DO NOT SEND FEES OR COMPLETE FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO			Complete if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Application Number	10/617,038	
			Filing Date	July 11, 2003	
			First Named Inventor	Andersen et al	
			Group Art Unit	1645	
			Examiner Name	SWARTZ	
			Attorney Docket Number	SSISAUSA	
Sheet	2	of	3		

OTHER PRIOR ART-NONPATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), column(s), number(s), publisher, city and/or country where published	T ²	
D E F G H I J K L	D	SAMBROOK ET AL, molecular cloning, A laboratory manual, Cold Spring Harbor Laboratories, NY, (1989) XP-002091112		
	E	Anon. Global Tuberculosis Control, WHO Report. (2001)		
	F	BRANDT ET AL, ESAT-6 Subunit Vaccination against Mycobacterium Tuberculosis, Infection and Immunity, Vol. 68, No. 2, pp. 791-795 (Feb. 2000)		
	G	BOON ET AL, Journal of Bacteriology, Vol. 183, No. 8 pp. 2672-2676, (April 2001)		
	H	DOHERTY ET AL, Immune Responses to the Mycobacterium Tuberculosis-Specific Antigen ESAT-6 Signal Subclinical Infection among Contacts of Tuberculosis Patients, Journal of Clinical Microbiology, Vol. 40, No. 2, pp. 704-706, (February 2002)		
	I	FLORCZYK ET AL, Identification and Characterization of Mycobacterial Proteins Differentially Expressed under Standing and Shaking Culture Conditions, Including Rv2623 from a Novel Class of Putative ATP-Binding Proteins, Infection and Immunity, Vol. 69, No. 9, pp. 5777-5785, (September 2001)		
	J	HARBOE ET AL, B-Cell Epitopes and Quantification of the ESAT-6 Protein of Mycobacterium Tuberculosis, Infection and Immunity, Vol. 66, No. 2, pp. 717-723, (February 1998)		
	K	MANGANELLI ET AL, The Mycobacterium Tuberculosis ECF Sigma Factor σ^E : Role in Global Gene Expression and Survival in Macrophages, Molecular Microbiology, Vol. 41, No. 2, pp. 423-437, (May 2001)		
	L	MONAHAN ET AL, Differential Expression of Mycobacterial Proteins Following Phagocytosis by Macrophages, Microbiology, 147, pp. 459-471, (2001)		
Examiner Signature	R P Swartz		Date Considered	10-19-05

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

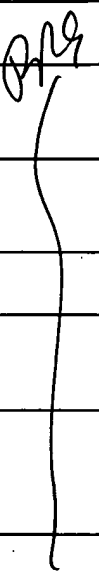
¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETE FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Application Number	10/617,038
		Filing Date	July 11, 2003
		First Named Inventor	Andersen et al
		Group Art Unit	1645
		Examiner Name	SWARTZ
Sheet 3 of 3	Attorney Docket Number	SS15AUSA	

OTHER PRIOR ART-NONPATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), coloumeousse number(s), publisher, city and/or country where published	T ²	
	M	RAVN ET AL, Human T Cell Responses to the ESAT-6 Antigen from Mycobacterium Tuberculosis, The Journal of Infectious Diseases, 179, pp. 637-45, (1999)		
	N	ROSENKRANDS ET AL, Identification an Characterization of a 29-Kilodalton Protein from Mycobacterium Tuberculosis Culture Filtrate Recognized By Mouse Memory Effector Cells, Infection and Immunity, Vol. 66, No. 6, pp. 2728-2735, (June 1998)		
	O	ROSENKRANDS ET AL, Hypoxic Response of Mycobacterium Tuberculosis Studied by Metabolic Labeling and Proteome Analysis of Cellular and Extracellular Proteins, Journal of Bacteriology, Vol. 184, No. 13, pp. 3485-3491, (July 2002)		
	P	SHERMAN ET AL, Regulation of the Mycobacterium Tuberculosis Hypoxic Response Gene Encoding α -Crystallin, PNAS, Vol. 98, No. 13, pp. 7534-7539, (June 19, 2001)		
	Q	SKJØT ET AL, Comparative Evaluation of Low-Molecular-Mass Proteins form Mycobacterium Tuberculosis Identifies Members of the ESAT-6 Family as Immunodominant T-Cell Antigens, Infection and Immunity, Vol. 68, No. 1, pp. 214-220, (January 2000)		
	R	VORDERMEIER ET AL, Correlation of ESAAT-6- Specific Gamma Interferon Production with Pathology in Cattle Following Mycobacterium Bovis BCG Vaccination against Experimental Bovine Tuberculosis, Infection and Immunity, Vol. 70, No. 6, pp. 3026-3032, (June 2002)		
Examiner Signature	R.P. Swartz		Date Considered	10-19-05

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETE FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



* **EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETE FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.**



PTO/SB/088 (08-00)
Approved for use through 4/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/617,038
				Filing Date	July 11, 2003
				First Named Inventor	Andersen et al
				Group Art Unit	1614 / 645
Examiner Name	SWARTZ				
Sheet	2	of	2	Attorney Docket Number	SSI5AUSA

OTHER PRIOR ART-NONPATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), coloumeousse number(s), publisher, city and/or country where published	T ²	
	T	MERRIFIELD, Solid Phase Peptide Synthesis. I. The Synthesis of a Tetrapeptide, J. Am. Chem. Soc., 85:2149, (July 20, 1963)		
	U	PEARSON ET AL, Improved Tools for Biological Sequence Comparison, Proc. Natl. Acad. Sci., Vol. 85, pp. 2444-2448, (April 1988)		
	V	ROLPH ET AL, Recombinant Viruses as Vaccines and Immunological Tools, Curr. Opin. Immunol. 9:517-24, (1997)		
	W	ULMER ET AL, Polynucleotide Vaccines, Curr. Opin. Invest. Drugs, 2(9):983-989 (1993)		
Examiner Signature	R.P. Swartz		Date Considered	10-19-05

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.
 This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETE FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



Under the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it contains a valid OMB control number.

PTO/SB/08B (08-00)
Approved for use through 4/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

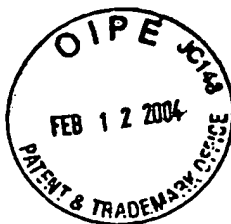
Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete If Known	
				Application Number	10/617,038
				Filing Date	July 11, 2003
				First Named Inventor	Andersen et al
				Group Art Unit	1614/1645
				Examiner Name	SWARTZ
Sheet	1	of	2	Attorney Docket Number	SSISAUSA

OTHER PRIOR ART-NONPATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number(s), publisher, city and/or country where published	T ²	
RPS	X	COTE-SIERRA ET AL, A New Membrane-bound OprI lipoprotein Expression Vector High Production of Heterologous Fusion Proteins in Gram (-) Bacteria and the Implications for Oral Vaccination, Gene 221 pp. 25-34, (August 10, 1998)		
	Y	GOSSELIN ET AL, Enhanced Antigen Presentation Using Human Fcγ Receptor (Monocyte/Macrophage)-Specific Immunogens, The Journal of Immunology, Vol. 149, No. 11, pp. 3477-3481 (December 1, 1992)		
	Z	HÖNER ZU BENTRUP ET AL, Mycobacterial Persistence: Adaptation to a Changing Environment, Trends in Microbiology, Vol. 9, No. 12, pp. 597-605, (December 2001)		
	AA	KILGUS ET AL, Analysis of the Permissive Association of a Malaria T Cell Epitope with DR Molecules, The Journal of Immunology, Vol. 146, No. 1, pp. 307-315, (January 1, 1991)		
	BB	KOHLER ET AL, Continuous Cultures of Fused Cells Secreting Antibody of Predefined Specificity, Nature, Vol. 256 (5517):pp. 495-7, (August 7, 1975)		
	CC	LOWRIE ET AL, Therapy of Tuberculosis in Mice By DNA Vaccination, Nature, Vol. 400, pp. 269-271, (July 15, 1999)		
	DD	LUSTIG ET AL, Humoral and Cellular Responses to Native Antigen Following Oral and Parenteral Immunization with Lipid-Conjugated Bovine Serum Albumin, Cellular Immunology, 24, pp. 164-172, (June 1, 1976)		
	EE	MCCAFFERTY ET AL, Phage Antibodies: Filamentous Phage Displaying Antibody Variable Domains, Nature Vol. 348, pp. 552-554, (December 6, 1990)		
	FF	MOWAT ET AL, Immune-Stimulating Complexes Containing Quil A and Protein Antigen Prime Class I MHC-restricted T Lymphocytes In Vivo and are Immunogenic by the Oral Route, Immunology, 72, (3), pp. 317-322, (March 1991)		
Examiner Signature		RPS Swartz	Date Considered	10-19-05

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETE FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

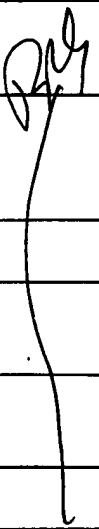
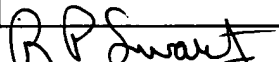


PTO/SB/08B (08-00)

Approved for use through 4/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete If Known	
				Application Number	10/617,038
				Filing Date	July 11, 2003
				First Named Inventor	Andersen et al
				Group Art Unit	614 1645
				Examiner Name	SWARTZ
Sheet	2	of	2	Attorney Docket Number	SSISAUSA

OTHER PRIOR ART-NONPATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), column(s), publisher, city and/or country where published	T ²
	GG	NAGAI ET AL, Isolation and Partial Characterization of Major Protein Antigens in the Culture Fluid of Mycobacterium Tuberculosis, Infection and Immunity, Vol. 59, No. 1, pp. 372-382, (January 1991)	
	HH	STRYHN ET AL, Peptide Binding Specificity of Major Histocompatibility Complex Class I Resolved into an Array of Apparently Independent Subspecificities: Quantitation by Peptide Libraries and Improves Prediction of Binding, Eur. J. Immunol. 26, pp. 1911-1918, (August 1996)	
	II	ROLPH ET AL, Recombinant Viruses as Vaccines and Immunological Tools, Curr. Opin. Immunol. 9, 4, pp. 453-5, (August 1997)	
	JJ	OLSEN ET AL, Efficient Protection Against Mycobacterium Tuberculosis by Vaccination with a Single Subdominant Epitope from the ESAT-6 Antigen, 30, 6, pp. 1724-1732, (June 2000)	
	KK	THOMPSON ET AL, Clustal W: Improving the Sensitivity of Progressive Multiple Sequence Alignment Through Sequence Weighting, Position-Specific Gap Penalties and Weight Matrix Choice, Nucleic Acids research, Vol. 22, No. 22, pp. 4673-4680, (November 11, 1994)	
	LL	VAN PINXTEREN ET AL, Control of Latent Mycobacterium Tuberculosis Infection is Dependent on CD8 T Cells, Eur. J. Immunol. 30, 12, pp. 3689-3698, (December 2000)	
Examiner Signature			
Date Considered		10-14-05	

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETE FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.